

paragraph [0060] (“The user can also completely customize the list boxes.”) paragraph [0061].

Claim 5, as previously amended, states that the template manger comprises a means for editing *all aspects* of the data entry screens.

***Claim Rejections 35 U.S.C §103***

The Examiner has rejected claims 2, 4, 5-6, 8, 13-16, 19, 20-21, 23-25, and 35-36 under 35 U.S.C §103(a) based on the conclusion it would have been obvious to combine the teachings of Brown with the teachings of Campbell et al, Ballantyne et al and Kehr et al. After thorough review of the cited prior art and examination of the Examiner’s arguments, the applicants concede that the Examiner has established a *prima facie* case for obviousness but hereby present additional evidence to rebut the case and show why the claimed invention is not obvious.

As stated by the CCPA, “once *prima facie* obviousness is found, the burden shifts to the appellant to rebut it, if he can, with objective evidence of nonobviousness.” *In re Fielder*, 176 USPQ 300, 302 (CCPA 1973). In determining whether subject matter would have been nonobvious under Section 103, the Examiner must determine the scope of content of the prior art, ascertain the differences between the prior art and the claims at issue, and define the level of ordinary skill in the pertinent art. Against this background, the Examiner determines whether the subject matter would have been obvious to a person of ordinary skill in the art at the time of the asserted invention. In making this determination, the Examiner can assess evidence related to secondary indicia of nonobviousness like commercial success, long-felt but unresolved needs, and the failure of others. *In re Kahn*, 78 USPQ2d 1329 at 1335 (Fed. Cir. 2006). See also *In re Kumar*, 76 USPQ2d 1048 at 1050 (Fed. Cir. 2005) (“An applicant may rebut a *prima facie* case of obviousness by providing a ‘showing of facts supporting the opposite conclusion.’ Such a showing dissipates the *prima facie* holding and requires the examiner to consider all of the evidence anew.”) (*emphasis in original*). Finally, there is no requirement that a patent applicant’s evidence and/or arguments traversing a

103 rejection must be contained within the specification. See *In re Chu*, 36 USPQ2d 1089 at 1095 ((Fed. Cir. 1995).

The Applicants thus set forth objective evidence to show that the claimed subject matter would have been nonobvious. The Applicants respectfully request the Examiner consider the following rebuttal evidence including such secondary considerations as commercial success, long-felt but unsolved needs and failure of others.

Regarding a long-felt but unresolved need for the claimed subject matter, The Applicants recognize such facts are not the kind that cannot be questioned, and indeed that the Federal Circuit has held that precedent requires the Applicant to submit actual evidence of long-felt need rather than simply arguing such need existed. *In re Kahn*, 441 F.3d 977, 78 USPQ2d 1329 (Fed. Cir. 2006). Thus, in addition to the attached Declarations is evidence to show the Federal government has mandated that all Pre-hospital providers to collect data electronically. Exhibit 1 (Goals and Objectives of the National EMS Information System), and Exhibit 2 (the NHTSA's Agenda for the Future Implementation Guide, *see specifically* page 4 under the heading 'Information Systems') are indicative of this move toward electronic data recordation for EMS providers. Indeed, the "Agenda for the Future" was first provided as far back as 1998, as evidenced by the history of NEMSIS timeline shown in Exhibit 3.

This and other factors described below have prompted a trend in the EMS industry toward the electronic collection of data while the EMS technician is still in the field. Davis Declaration ¶4. In many departments, such practices are recommended while in many others they are in fact required. *Id.*

Logically, there are financial reasons to implement such a system as well. For instance, conventionally there is a great deal of paper and physical files associated with medical data collection. Davis Declaration ¶4. For billing purposes, storage purposes and record keeping purposes, these documents are often moved, copied and mailed at great expense. *Id.* In addition, statistics and checks on the number of procedures performed by each technician are recorded for quality assurance purposes, and such data is more

easily tracked electronically. Id. Moving to electronic record keeping is known to reduce these downsides as well as allow for better and often complete documentation and fewer lost calls due to oversight and physical papers being misplaced. Id. Finally, electronic data collection vastly improves the ability to track the effectiveness of current paramedicine in general. Id. This movement has been ongoing since at least the time of filing the present application. Id. There is thus a long-felt need for an electronic data collection system that can be used in the field.

As expected, the need to move to electronic data collection prompted many companies to attempt to provide suitable products. Davis Declaration ¶¶4. Indeed, competitors to the Applicants have built software for handheld platforms, but all have failed. Hood Declaration ¶¶5. The claimed subject matter in the present application has proven to work and be commercially successful whereas competitors' attempts have met with failure. Id.

The failure of others has to do with one of the claimed elements of the present invention, namely, the customizable nature of the system and its adaptability to small screens. From department to department and region to region, there are large differences in data collection requirements and requirements for interfacing with and documenting medical data. Davis Declaration ¶¶7. In order to create a system complex enough to meet the various documentation needs and to display and collect essentially unlimited amounts of data on a small handheld screen, the Applicants developed the customized template approach defined in the specification and claims as "Template Manager". Hood Declaration ¶¶6.

Prior to the unveiling of the system claimed in the present application, solutions were rigid designs with minimal ability to adapt to the various demands of different departments. Davis Declaration ¶¶8. For instance, many competitors created systems for large governmental departments due to their use of the common Advanced Life Support (ALS) transporting standard and because customization costs for these larger systems were more easily recuperated. Id. Systems with customization capabilities to

meet the needs of small and rural departments were not available before the introduction of the claimed system. Hood Declaration ¶¶7. The small departments are having difficulty meeting the federal mandate because not only do they have less funding to do so, but also because their small size does not allow competing systems to recuperate customization startup costs. Id.

Due to the high levels of customization offered by the present system, it has met the requirements for a wide variety of departments including very small departments, non-transporting departments, DIALYSIS and 'gurney car' services, etc. Hood Declaration ¶¶8. The success of the present system was based on the ability to use templates to create a system allowing the collection of wide range of data on a small screen. Id. The needs of these departments have been unmet by competing systems. Id.

Nearly all competitors have also attempted some sort of handheld hardware platform for EMS, but all have failed. Hood Declaration ¶¶9. The attempt of these competitors to develop the system again shows that there does exist a need for such a system. Id. The present system is the only system commercially successful on pocket-pc sized handheld devices, and meets the needs of providing a handheld hardware platform for EMS. Id. It is the high level of customization that has allowed the present system to be deployed for departments using displays as small as PDA type mobile phones. Id. Through use of the claimed template driven system of creating widely customizable interfaces for such displays, even small departments with specialized needs have quickly created and rolled out a handheld platform for EMS. Id.

As stated above, competitors have attempted to deploy a handheld hardware platform for EMS but have failed. Hood Declaration ¶¶10. Most failures stem from the fact that systems designed to work on PC screens do not translate well to handheld screens. Id. Even large corporations such as Zoll and Medtronic have entered the market and had failures. Id. For instance, Medtronic pulled its system from the market because the system could not "adapt" or be customized to the customers' needs. Id. Furthermore, Zoll, the industry leader with the largest market share also pulled from the market a

product that was an attempt at a handheld version of their software used on larger displays. Id. Such failures show the inherent problem of having success in displaying and collecting data for EMS Data collection on a small handheld device. Id. Other industry leaders, such as Med Media, attempted to produce successful handheld data recording devices for EMS but have since pulled their products because of failure. Id. The present application's disclosure and claims covering an approach of using customizable templates has made the Applicants' system vastly superior to systems implemented before it. Davis Declaration ¶9.

Regarding the commercial success of the system covered by the pending claims, the system is now in use in six states, with three military contracts, and is the main system used in San Diego County, which is the 6<sup>th</sup> largest EMS system in the United States. Hood Declaration ¶11. Furthermore, the system has not been the subject of significant advertising. Id. Unexpectedly, the customizable nature of the system has even allowed it to find success on very small mobile platforms. Id. Hence, the system has even been deployed on mobile phones, which due to their small size and the fact that they are already carried by ambulance and fire personnel are the ideal platform to meet state and locally mandated EMS agency requirements for ambulances. Id.

### ***Conclusion***

The facts detailed above, along with the attached supporting evidence, show the recognition of a problem, the failure of others to meet the long-felt need, and the commercial success of the current Applicants' system to meet this need. The objective evidence presented above supports the conclusion that the invention would not have been obvious to a skilled artisan and that the prior art did not enable one skilled in the art to produce the now-claimed invention.

In light of the remarks and amendments detailed above, which address each rejection and objection by the Examiner, the Applicants respectfully request reconsideration and allowance of all pending claims.

Respectfully Submitted,

**TEMMERMAN LAW OFFICE**

A handwritten signature in black ink, appearing to read 'MATHEW J. TEMMERMAN', is written over a horizontal line.

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Dated: October 7, 2008